CACOACO

510(K) SUMMARY STAR DENTAL LOW SPEED MOTORS AND ATTACHMENTS

Company:

Star Dental, Division of Den-Tal-Ez, Inc. Owner/operator number <u>2520265</u>

MAR 28 1996

Contact Person:

Jeff Peinhardt
Quality Assurance Manager
Star Dental, Division of Den-Tal-Ez, Inc.
1816 Colonial Village Ln.
Lancaster, PA 17601
Phone (717) 291-1161
Fax (717) 291-3249

Device Trade Name:

Star Dental TITAN Series Motors and Attachments

Common or Usual Name:

Low Speed Motors and Attachments

Predicate Devices:

Star Dental TITAN Series Motors and Attachments, Micro Motors, Nakinishi Dental, KAVO, and Lares low speed motors.

Description/Intended Use:

Air powered low speed dental motor that powers various dental attachments and accessories to facilitate procedure by the dental clinician during routine dental procedures.

Substantial Equivalence:

The Low Speed air-powered motor as submitted is substantially equivalent to other motors currently being marketed by, Micro Motors, Nakinishi Dental, KAVO, and Lares. Materials used to manufacture the components are similar. Means of operation are identical, compressed air powers a variable speed rotary vane motor to provide power for various dental procedures. The performance specifications are virtually identical. The differentiation between the predicate device and the submitted one is more precise speed control, spring pre-loaded bearings.